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February **16**, 2000

Department of Health and Human Services Assistant Secretary for Planning and Evaluation Attention: Privacy-P, Room G-322A Hubert H. Humphrey Building 200 Independence Avenue, SW Washington, DC 20201

Re: Proposed Privacy Standards -- 64 Fed. Reg. 59978 (Nov. 3, 1999)

Dear Assistant Secretary:

The National Council for Prescription Drug Programs (NCPDP) is pleased to submit the following comments regarding the proposed privacy standards for individually identifiable health information.

NCPDP is a non-profit ANSI-accredited Standards Development Organization consisting of more than 1,100 members who represent computer companies, drug manufacturers, pharmacy chains and independents, drug wholesalers, insurers, mail order prescription drug companies, pharmaceutical claims processors, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies and other parties interested in electronic standardization within the pharmacy services sector of the health care industry.

Although NCPDP supports keeping patient identifiable information confidential it cannot support these proposed privacy regulations as written because they completely miss their stated goal of "administrative simplification" for the specific reasons outlined in our comments below. In addition, the proposed privacy regulations not only put an undue administrative and financial burden on the covered entities, but also could adversely impact patient health care by delaying individual health care services, and reducing the sharing of patient information that is essential for the provision of optimal patient care.

Applicability-sections 164.104 and 164.502 (F.R. page 60052).

The proposed regulations are much broader than their very narrow and restrictive enabling legislation... section 264(c)(i) of the Health Insurance Portability and Accountability Act of 1996 (HIPAA):

"If legislation governing standards with respect to the privacy of individually identifiable health information transmitted in connection with the transactions described in section 1173(a) of the Social Security Act (as added by section 262) is not enacted by the date that is 36 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall promulgate final regulations containing such standards not later than the date that is 42 months after the date of the enactment of this Act."

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The Congressional mandate is clear... the proposed privacy standards regulations must only apply to the privacy of individually identifiable health information as it is transmitted in connection with the transactions described in section 1173(a). Only individually identifiable health information contained in these electronically transmitted transaction standards may be the subject of these proposed privacy standards regulations. Therefore, these proposed privacy regulations must be rewritten to conform to the intent of Congress.

In addition, Congress only authorized the Secretary to "promulgate final regulations containing such **standards**" (Emphasis added.) <u>not</u> the implementation specifications that represent most of the proposed privacy regulations.

Not only should these implementation specifications be eliminated because they were not authorized by Congress, but also to allow the covered entities to tailor their own implementations of the federal standards resulting in maximum flexibility and scalability that is "consistent with good health professional practices and ethics".

Consistent with the statutory interpretation immediately above, NCPDP does not believe that paper records are, or should be, covered by these proposed regulations. However, if they were, it would seem difficult if not impossible to determine what paper is subject to the proposed regulations and what paper is not.

NCPDP does not believe that the privacy regulations should attempt to create a protection distinction between more sensitive patient identifiable health care information. This distinction would be far too subjective resulting in uneven implementation of the proposed regulations resulting in increased liability for the covered entities in addition this would probably result in delayed health care services for individuals as the entities attempt to determine what they must legally do under a plethora of individual factual situations.

Definitions -section 160.103 (F.R. page 60049)

"Health care clearinghouse"... The definition of "health care clearinghouse" must be amended by adding "intermediaries" to the list in the sentence that begins with, "Billing services, repricing companies...".

Definitions-section 164.504 (F.R. page 60052).

"Disclosure"... The definition of "disclosure" must be amended by adding at the end of that definition "other than to the individual who is the subject of the information". This change would make it clear that a health care provider may release an individual's protected information to that individual without first requiring that the patient complete an authorization form.

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"Payment"... (page **60053**)... the definition of "payment" must be amended by replacing "medical data processing" with the broader term "related healthcare data processing".

It is necessary to draw this line as clearly as possible so that the covered entities know what they can and can not do. NCPDP offers the following minor changes that would facilitate the maximum disclosure of information to an individual without requiring that individual to complete the authorization form and also to better reflect the intent languageonpage60003:

"Only those covered entities who disclose health information to marketers, reporters, privacy investigators, researchers, and others for purposes **unrelated** to treatment, payment, and health care operations are required to get the written consent of the patient in accordance with this rule." (Emphasis added.)

Third Party Beneficiary to Business Partner Contract...Section 164.506(e)(2)(ii)(A) (F.R. page 60055).

This provision creates uncertainty whether or not switches, value-added networks, other important participants in the claims transmission process, pharmacists, insurance companies, and **PBMs** will be considered "business partners". For these reasons, we recommend that this provision must be rewritten.

This provision would also provide a new federal right of action for individuals in those states that recognize a cause of action if a party is named in a contract as a third party beneficiary. Congress did not authorize nor intend that the Secretary provide a new cause of action for a breach of a business partner contract required by these proposed privacy regulations. For this reason this provision must be deleted.

Authorization Required... section 164.580 (F.R. page 60055-60056).

The Authorization for Release of Information form on page 60065 must be clarified for the benefit of both covered entities and individuals. The last sentence on that Authorization form must be rewritten to better reflect section 164.508(a)(2)(iv): "No authorization is necessary to use or disclose protected health information to carry out treatment, payment, or health care operations, except when the information to be released is psychotherapy notes or research information that is unrelated to treatment."

Disclosures for Banking and Payment Processes... Section 164.510(i) (F.R. page 60058).

This subsection must be clarified to assure that pharmacy benefit cards are not considered "or other payment card, or other payment means...". Otherwise, the National Council for Prescription Drug Programs (NCPDP) payment claim, which is expected to be adopted by HHS as the national pharmacy payment claim, may have to

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be modified to only provide the "minimum amount of protected health information necessary to complete a banking or payment activity...".

In addition to payment, the NCPDP payment claim also facilitates concurrent drug utilization review. Because of its importance in improving patient care, concurrent drug utilization review was mandated by Congress in the Omnibus Budget Reconciliation Act of 1990 (OBRA 90). Although NCPDP's role is not as the entity conducting such reviews, NCPDP electronic payment claim format creates the real-time ability for pharmacies to have access to information that may be necessary to meet the requirements of this federal and similar state laws.

Health care information carried on an NCPDP payment claim goes beyond claims payment and may include information that could be used to provide professional pharmacy services, such as compliance, disease management, and outcomes programs. Such information must not be arbitrarily restricted by the application of the "minimum necessary standard".

The "minimum necessary standard" will also be impossible to implement concerning the information provided on the NCPDP payment claim to pharmacies for concurrent drug utilization review. The "minimum necessary standard" is completely at odds with trying to provide as much information as possible to help assure that optimal care can be provided. It is very <code>naïve</code> for HHS to believe that health care providers will know in advance what patient information they will need in order to provide optimal patient care. In addition, it is just as naive for HHS to believe that covered entities providing this information to providers will be able to determine what is the "minimal" amount. The "minimal necessary standard" will surely have a chilling effect on sharing patient identifiable health care information resulting in less than optimal patient care and resulting in increased malpractice litigation. In short, the "minimum necessary information standard" is bad public policy and for the reasons stated above should be deleted.

Non-Preemption of State Law... subpart B (F.R. pages 60050 and 60051).

Lack of Federal preemption will make it difficult if not impossible for covered entities to know what law they must follow. This is more than a mere inconvenience and expense to the covered entities... individual patients will likely suffer when their health care is interrupted while they wait while the covered entities struggle to try to understand what law to follow.

Conflicts between these proposed regulations and state laws would occur because of the lack of federal preemption. The practical significance is that the covered entities would have to know... for every conceivable factual situation that could present itself... the applicable state law, federal law, whether or not a conflict exists between these two bodies of law, and finally how to resolve that conflict correctly under the penalty of law.

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There probably are not enough lawyers available to the covered entities that would be necessary to determine immediately what law must be followed in the real-time of electronic transactions and patients waiting for their prescriptions. The only solution would appear to have Congress enact privacy legislation that does preempt state law. Without federal preemption of state privacy laws these proposed regulations are fatally flawed and therefore should not be finalized.

Disclosures by Whistleblowers... section 164.518(a)(4) (F.R. pages 60062).

This "implementation specification" should be rewritten in a less confrontational tone. Specifically, a would be whistleblower should first be required to raise the issue of a possible violation of these regulations with the covered entity before going to an attorney, oversight agency, or law enforcement official. The proposed regulations should assume that the covered entities will act in good faith to comply with these privacy requirements.

Any meaningful government-private sector "administrative simplification" effort must be based upon cooperation and mutual respect, not on government actions that alienate employees from their employer. Compliance in good faith should be presumed... not only in this provision, but also in all of the proposed regulatory provisions. Sufficient punitive provisions are included in these proposed regulations to address the exceptions to this general good faith presumption.

Compliance and Enforcement... section 164.522 (F.R. pages 60063 and 60064).

Section 164.522(b) should be modified to allow 90 days for the covered entities to resolve the complaint before the individual may submit that complaint to the Secretary. The Secretary already has this authority to make this suggested change... section 164.522(b)(1)(iii): 'The Secretary may prescribe additional requirements for the filing of complaints...". This suggested change would reduce the administrative burden on the Secretary and, even more importantly, encourage the covered entities to work out complaints with their patients. Again, the regulations should reflect a presumption that covered entities will act in good faith in complying with government regulations... it is not a good business practice to act in ways that will drive your patients to your competitors.

Costs of Implementing the Privacy Regulations as Proposed is Likely to be Much Higher than the Secretary has Estimated.

Although time did not permit, NCPDP estimates that the proposed regulations will add substantial costs to the pharmacy claims adjudication system. The proposed regulations will require changing the NCPDP payment claim format to include a field to notify future users that the individual has contested the accuracy of at least a part of the drug payment claim information.

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The contested notice will take up additional bytes of space, which generates a number of associated costs: reprogramming the claims processing system and the costs of processing the increased record length and storage costs for the extra information.

HHS estimates the "cost of compliance with the proposed rule would be at least \$3.8 billion over five years" (F.R. page 60006). However, the October 19, 1999, Report by BlueCross BlueShield Association (by Robert E. Nolan Company) of similar proposals, many of which are included in this proposed rule, estimates cost at over 10 times that amount... \$43 billion over five years.

However, cost should not be viewed in a vacuum. What will all the money required to be spent by these proposed regulations buy? According to HHS at F.R. page 59923... "the HIPAA legislative authority is more limited in scope than the federal statute we recommend, and does not always permit us to propose the policies we believe are optimal". Buying less than optimal privacy protection does not sound like a good bargain for the covered entities or the American people.

We agree with the Secretary that "there is an urgent need for legislation to establish comprehensive privacy standards for all those who pay and provide for health care, and those who receive information from them". (F.R. page 59923)

These proposed regulations should not be implemented because they are not as comprehensive as they must be to provide optimal privacy protection for patient identifiable health care information and could delay health care services to individuals. Federal privacy legislation that preempts state law is the only reasonable solution to resolve this issue and we urge Congress to make it their number one domestic priority this year.

Sincerely,

Lee-Ann C. Stember

President

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Steffenie Peterson

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York Prescription Benefits Management

James Bigl

Voting Ctgy: **G** Member Count: 1

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